CLARUS MEDICAL

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510(K) SUMMARY

K011454

DEC 1 3 2001

Model 2180 Spinescope Endoscope

General Information

Classification	Class II
Trade Name	Clarus Model 2180 Spinescope
Common Name	Spinal Endoscope
Submitter	Clarus Medical, LLC 1000 Boone Avenue North Suite 300 Golden Valley, Minnesota 55427
Contact	Tom Barthel, President Telephone: (763) 525-8401 Fax: (763) 525-8656
Summary Date	April 23, 2001

Predicate Devices

501(k) Number	Trade or Proprietary or model name	Manufacturer
K945296	Model 2170, Phoenix Neuro Endoscope	Clarus Medical, LLC
K940144	Model 2160, Channelflex Percutaneous Spinescope	Clarus Medical, LLC
K923514	Model 2150, Spinescope	Clarus Medical, LLC
K922881	Model 1101, LASE Kit	Clarus Medical, LLC
K913136	Model 1100, LASE Kit	Clarus Medical, LLC
K912089A	Model 2100, Endoscope	Clarus Medical, LLC

Description

The SPINESCOPE has a tip outer diameter of 2.3 mm, a working channel inside diameter of 1.0 mm, a working length of 12 cm, a working channel length of 27 cm, and an overall length of approximately 100cm. The SPINESCOPE is actively deflectable and has a working channel for instruments currently marketed for endoscopic use, or for irrigation. The viewing optics have a 0 degree (straight forward) direction of view, and a field of view of 70 degrees in air and 50 degrees in water. The tip of the endoscope deflects to 45 degrees in an upward direction (towards the sliding deflection tab on the handle).

Intended Use

The Model 2180 SPINESCOPE endoscope is intended for intraoperative or percutaneous accessing and visualizing spinal nerve roots, and surrounding tissue in the cervical spine. It is commonly used via the anterior approach to the cervical spine. **The SPINESCOPE is intended for single use only.**
Do not re-sterilize.

Indications for Use

Visual inspection of the cervical spinal nerve roots and surrounding tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Tom Barthel
President
Clarus Medical
1000 Boone Avenue, North
Suite 300
Golden Valley, Minnesota 55427

Re: K011454
Trade Name: Spine Scope, Clarus Model 2180
Regulation Number: 888.1100
Regulation Name: Arthroscope and Accessories
Regulatory Class: II
Product Code: HRX
Dated: December 5, 2001
Received: December 6, 2001

Dear Mr. Barthel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011454

Indications for Use

Visual inspection of the cervical spinal nerve roots and surrounding tissue.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011454